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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/801,185   | 03/07/2001  | Jochen G. Salfeld    | BBI-043CPUSCN       | 1672             |
| 959  | 7590        | 10/23/2006           | EXAMINER            |                  |
| LAHIVE & COCKFIELD, LLP<br>ONE POST OFFICE SQUARE<br>BOSTON, MA 02109-2127 |             |                      | SAUNDERS, DAVID A   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1644                |                  |
| DATE MAILED: 10/23/2006  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/801,185

Applicant(s)

SALFELD ET AL.

Examiner

David A. Saunders, PhD

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 114-121 and 141-188 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 114-121 and 141-188 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicant's response filed on 8/9/06 has been entered.

The claims pending and under examination are 114-121 and 141-166.

Claims 118, 147 and 155 are objected to because of the following informalities:  
In these claims " $10^{-8}$  m" should appear as " $10^{-8}$  M". Appropriate correction is required.

The following grounds of rejection are maintained.

Claims 141-142 are 159-166 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-40 and 49 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the issued claims. See reasons of record in action of 2/9/06.

Claims 114-121 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the issued claims. See reasons of record in action of 2/9/06.

Claims 143-150 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the issued claims. See reasons of record in action of 2/9/06.

Claims 151-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably

Art Unit: 1644

distinct from each other because the instant claims are encompassed by the issued claims. See reasons of record in action of 2/9/06.

References C4 and C11 (submitted with IDS of 12/9/05) have been considered. The most relevant of these references is that of Jespers et al (C4), which discloses a human Fab that binds to human TNF with a  $K_d$  of 15 nM (by a Klotz plot) or 11 nM (by a Scatchard plot); see p 901, col. 1, 1<sup>st</sup> para. These values are within the experimental error range of applicant's recited limit of  $10^{-8}$  M. It is noted, however, that the epitope to which this antibody binds is the same as that bound by rodent antibody Mab32. Mab32 is art known to enhance rather than neutralize TNF activity (e.g. see 6,593,458 at col. 15, line 15; col. 16, lines 14-15). Therefore, the antibody of Jespers et al is not relevant to instant claims 114, 118, 141, 143, 147, 151 and 155.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 10/17/06 DAS

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 1644